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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,916

11/21/2003

Paul Edward Kearney

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7002

33721

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07/18/2008

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CANADA

EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,916	<b>Applicant(s)</b> KEARNEY ET AL.	
	<b>Examiner</b> JERRY LIN	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 13-20, 23, 25-32, 35, 37-44, 47, 49-56, 59 and 61-110 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-8,13-20,25-32,37-44,49-56,63,65,67,69,73,75,77,79,83,85,87,89,93,95,97,98,103,105,107 and 108.

Continuation of Disposition of Claims: Claims rejected are 11,23,35,47,59,61,62,64,66,68,70-72,74,76,78,80-82,84,86,88,90-92,94,96,99-102,104,106,109 and 110.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2008 has been entered.

### ***Status of the Claims***

Claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110 are under examination.

Claims 9, 10, 12, 21, 22, 24, 33, 34, 36, 45, 46, 48, 57, 58, and 60 are cancelled.

Claims 1-8, 13-20, 25-32, 37-44, 49-56, 63, 65, 67, 69, 73, 75, 77, 79, 83, 85, 87, 89, 93, 95, 97, 98, 103, 105, 107, and 108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, species or subspecies, there being no allowable generic or linking claim. Applicant timely traversed the species (election) requirement in the reply filed on 8/22/2007.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary – a great deal of experimentation would be required to determine how to transform the peptide maps based on retention time.

2) the amount of direction presented – the specification does mention that an algorithm is used to transform the peptide maps on pages 27-30, however, it does not teach the equations or methods used to perform the retention time transformation function.

(3) the presence or absence of working examples – there are no working examples,

(4) the nature of the invention – the invention appears to require computational methods to transform a peptide map.

(5) the state of the prior art – the prior art does not appear to teach transforming peptide maps using retention time transformation function. For example, Miliotis et al. “Protein Identification Platform Utilizing Micro-Dispensing Technology Interfaced to Matrix-Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry,” (2000) Volume 886, pages 99-110 teach a method of using chromatography for aligning peptide maps (abstract; page 104, 108, and 109). However, Miliotis et al. do not use a retention time transformation function to align their maps. Thus, it is unclear as to how one of skill in the art is to derive a retention time transformation function.

(6) the relative skill of those in the art – the skill is high.

(7) the predictability or unpredictability of the art – the biological sciences are considered an unpredictable art.

(8) the breadth of the claims – the claims include the step of deriving a retention time transformation function.

The instant claims include a step of deriving a retention time transformation function. According the Merriam Webster online dictionary, the relevant definitions of function is “a mathematical correspondence that assigns exactly one element of one set to each element of the same or another set” (for example,  $f(x) = y$ ) or “a variable (as a quality trait, or measurement) that depends on and varies with another” or “a computer subroutine; *specifically*: one that performs a calculation with variable provided by a program and supplies the program with a single result”. Although the specification does

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mention performing a transformation of the peptide map based on the retention time at pages 27-30, the specification does not teach how one of skill in the art is to derive a retention time transformation function. The specification does not include any mathematical equations, or teach how the retention time would modify the peptide maps, or teach any computer subroutines. Furthermore, a search of the prior art of peptide mapping utilizing LC/MS methods has not revealed a well-known method of deriving a retention time transformation function. As in the example above, the prior art reference of Miliotis et al. do not use a retention time transformation function to align their peptide maps. Thus, it is unclear as to how one of skill in the art is to derive a retention time transformation function. Given that the specification does not provide examples or guidance on how to derive a retention time transformation function, one of skill in the art would have to perform undue experimentation in order to determine the retention time transformation function needed to align different peptide maps.

#### Response to Arguments

4. Applicants have responded to this rejection by outlining the steps disclosed in the specification for aligning a peptide map as well as supplying a Declaration by Dr. Paul Kearney under 37 C.F.R. §1.132. The Applicants outline the steps of Determining Peptide Neighbors, Retention Time Clustering, Best Adjustment, Repeat and Optimizing, and Apply Adjustment. Dr. Kearney explains in his declaration that retention time clustering is well known in the art. While the Examiner agrees that outlined steps as well as retention time clustering are well known in the art, it is unclear if these steps or retention time clustering are the same as the recited retention time

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transformation function in the claims. The specification does not define a retention time transformation function as the outlined steps or as retention time clustering. Applicants also discuss each of the Wand factors, however the basis of their arguments rests on the outlined steps in the specification or retention time clustering. However, none of these steps disclose deriving a retention time transformation function. Because a retention time transformation function is not clearly defined as the outlined steps by the Applicants or as retention time clustering, one of skill in the art would not know what the function is or how to derive the function. Thus, the arguments and the Declarations under 37 CFR 1.132 filed 4/30/08 and 6/10/08 are insufficient to overcome the instant rejection of claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110. One of skill in the art would have to perform undue experimentation to determine the retention time transformation function needed to align different peptide maps.

### ***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 23, 47, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90, 101, 102, 104, 106, 108, and 110 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless



the claims include a practical application of that judicial exception as evidenced by a physical transformation of matter, or if the claimed invention recites a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. See MPEP 2106.

The instant claims do not produce a useful, concrete, and tangible final result. A useful, concrete, and tangible final result requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claim recites a final step of storing the results in a computer memory. However, a final step of storing the results in a computer memory would not necessarily require communication to the outside world. Thus, the claimed methods do not require a tangible final result. Examples of amendments to overcome this rejection include amending the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

#### Response to Arguments

7. Applicants have responded to this rejection by amending claims 61 to include outputting the final result to a user or display and amending claims 71, 81 and 101 to include storing the final result in computer memory. Instant claim 61 now recite a useful, concrete, and tangible result and the instant rejection is withdrawn as it was applied to claim 61 and its dependent claims. However, as explained above, storing a

result in a computer memory is not a tangible result as recited in claims 71, 81, and 101. Thus, instant claims 71, 81, and 101 and their dependences are non-statutory.

### ***Withdrawn Rejections***

8. Applicant's arguments and amendments, filed 4/30/2008, with respect to the rejections made under 35 U.S.C. §112 2<sup>nd</sup> and §101 as applied to claims 11, 61, 62, 64, 66, 68 and 70 have been fully considered and are persuasive. The amendments are sufficient to overcome these rejections. These rejections have been withdrawn.

### ***Conclusion***

No claim is allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L./

Examiner, Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631